

EXAMINER'S AMENDMENT

1. The non-final office action mailed 11/7/08 is vacated in favor of this examiner's amendment.
2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Donald Zuhn on 12/11/2008.

The restriction requirement between product and process claims originally set forth on 5/24/06 is hereby WITHDRAWN. An examiner's amendment which reenters product claims into this application is included in this office action. In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The application has been amended as follows:

In claim 23, the word "are" in the second line of the claim was deleted and the word --- were--- is inserted therefor.

In claim 24, the word “are” in the second line of the claim was deleted and the word --- were--- is inserted therefor.

In claim 25, the word “are” in the second line of the claim was deleted and the word --- were--- is inserted therefor.

The following claims were added:

Claim 26: A reagent for detecting human papilloma virus (HPV) DNA in a cell sample which indicates the patient providing the cell sample is at risk for cancer, comprising a plurality of genomic HPV DNA probe sets; wherein:

- (a) a first genomic HPV DNA probe set comprises a plurality of labeled nucleic acid fragments prepared by labeling essentially the full-length genomic sequence of HPV type 16, and which constitute approximately 8.3% of the total HPV DNA in the reagent,
- (b) a second genomic HPV DNA probe set comprises a plurality of labeled nucleic acid fragments prepared by labeling essentially the full-length genomic sequence of HPV type 18, and which constitute approximately 20.8% of the total HPV DNA in the reagent,
- (c) a third genomic HPV DNA probe set comprises a plurality of labeled nucleic acid fragments prepared by labeling essentially the full-length genomic sequence of HPV type 31, and which constitute approximately 8.3% of the total HPV DNA in the reagent,
- (d) a fourth genomic HPV DNA probe set comprises a plurality of labeled nucleic acid fragments prepared by labeling essentially the full-length genomic sequence of HPV type 33, and which constitute approximately 20.8% of the total HPV DNA in the reagent,

(e) a fifth genomic HPV DNA probe set comprises a plurality of labeled nucleic acid fragments prepared by labeling essentially the full-length genomic sequence of HPV type 35, and which constitute approximately 20.8% of the total HPV DNA in the reagent, and

(f) a sixth genomic HPV DNA probe set comprises a plurality of labeled nucleic acid fragments prepared by labeling essentially the full-length genomic sequence of HPV type 51, and which constitute approximately 20.8% of the total HPV DNA in the reagent;

wherein the labeled nucleic acid fragments of the genomic HPV DNA probe sets detectably hybridize to the genomic sequence of HPV types 39, 45, 52, 56, 58, 59, 68 and 70 in addition to detectably hybridizing to the genomic sequence of HPV types 16, 18, 31, 33, 35, and 51;

and wherein the labeled nucleic acid fragments of the genomic HPV DNA probe sets do not detectably hybridize to the genomic sequence of HPV types 42, 43, or 44.

Claim 27: A kit for detecting human papilloma virus DNA in a sample comprising a container containing the reagent of claim 26.

Priority

3. It is noted that all of the claims in this application are entitled to benefit of priority to the parent application 09/582492.

Double Patenting

4. The provisional obviousness type double patenting rejection set forth in the office action mailed 11/7/08 is hereby WITHDRAWN in accordance with MPEP 804 I(B)(1) which states, “If a “provisional” nonstatutory obviousness-type double patenting (ODP) rejection is the only

rejection remaining in the earlier filed of the two pending applications, while the later-filed application is rejectable on other grounds, the examiner should withdraw that rejection and permit the earlier-filed application to issue as a patent without a terminal disclaimer.”

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C Switzer whose telephone number is (571) 272-0753. The examiner can normally be reached on Tuesday or Wednesday, from 9:00 AM until 4:30 PM, and Thursday afternoon from 12:30 PM until 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Ram Shukla can be reached by calling (571) 272-0735.

The fax phone numbers for the organization where this application or proceeding is assigned are (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-0507.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO’s Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO’s Patent Electronic Business Center is a complete

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Juliet C. Switzer/
Primary Examiner
Art Unit 1634

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